EXHIBIT I

5-Year Longitudinal Followup after Retropubic and Transobturator Mid Urethral Slings

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Purpose: Few studies have characterized longer-term outcomes after retropubic and transobturator mid urethral slings.

Materials and Methods: Women completing 2-year participation in a randomized equivalence trial who had not undergone surgical re-treatment for stress urinary incontinence were invited to participate in a 5-year observational cohort. The primary outcome, treatment success, was defined as no re-treatment or self-reported stress incontinence symptoms. Secondary outcomes included urinary symptoms and quality of life, satisfaction, sexual function and adverse events.

Results: Of 597 women 404 (68%) from the original trial enrolled in the study. Five years after surgical treatment success was 7.9% greater in women assigned to the retropubic sling compared to the transobturator sling (51.3% vs 43.4%, 95% CI −1.4, 17.2), not meeting prespecified criteria for equivalence. Satisfaction decreased during 5 years but remained high and similar between arms (retropubic sling 79% vs transobturator sling 85%, p=0.15). Urinary symptoms and quality of life worsened with time (p <0.001), and women with a retropubic sling reported greater urinary urgency (p=0.001), more negative impact on quality of life (p=0.02) and worse sexual function (p=0.001). There was no difference in the

Abbreviations and Acronyms

KM = Kaplan-Meier

MESA = Medical, Epidemiological and Social Aspects of Aging

MUS = mid urethral sling

QOL = quality of life

SUI = stress urinary incontinence

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proportion of women experiencing at least 1 adverse event (p=0.17). Seven new mesh erosions were noted (retropubic sling 3, transobturator sling 4).

Conclusions: Treatment success decreased during 5 years for retropubic and transobturator slings, and did not meet the prespecified criteria for equivalence with retropubic demonstrating a slight benefit. However, satisfaction remained high in both arms. Women undergoing a transobturator sling procedure reported more sustained improvement in urinary symptoms and sexual function. New mesh erosions occurred in both arms over time, although at a similarly low rate.

Key Words: urinary incontinence, stress; suburethral slings

MID urethral slings are the most commonly performed surgeries for women with stress urinary incontinence. Approximately 200,000 SUI surgeries are performed annually in the United States, increasing 27% from 2000 to 2009.[1,2] Most of this increase is attributed to sling procedures.[3] Insufficient information is available regarding the long-term success and safety of MUS procedures as most previous clinical trials reported outcomes only at 1 to 2 years, and did not include physical examinations in the followup.

Failure rates increase with time for most SUI procedures.[4,5] Whether this is due to surgical failure or the natural history of incontinence with aging is unclear. Complications of SUI surgery, including urgency urinary incontinence, urinary tract infections and mesh related problems, may have a long-term impact on patient satisfaction and QOL. The Food and Drug Administration issued warnings about the use of mesh for prolapse and SUI surgery due to a lack of information regarding longer term outcomes. Mesh related complications can occur up to 5 years postoperatively.[5,6] Few prospective studies report long-term outcomes after MUS in a comparative fashion using validated symptom and QOL questionnaires and physical examination, which are essential for evaluating mesh complications.[5,7–9] Even fewer randomized trials compare continence outcomes and mesh complications between retropubic and transobturator slings with followup longer than 2 years.[10]

We previously reported 1 and 2-year outcomes of a randomized equivalence clinical trial of retropubic and transobturator MUS in women with SUI.[11,12] We report 5-year outcomes including treatment success, satisfaction, urinary symptoms, QOL and adverse events in women who completed the TOMUS (Trial of Mid-urethral Slings) and were enrolled in this observational cohort study.

METHODS

Study Design

Details of design and 1-year (primary outcome) and 2-year outcomes of the randomized equivalence trial of retropubic and transobturator MUS have been published (NCT00325039).[11,12] Women completing the trial who did not undergo surgical re-treatment for SUI were invited to participate in the observational study to assess 5-year treatment success, satisfaction, symptom specific distress, QOL and adverse events of MUS. Institutional review boards at each participating institution approved the observational followup study protocol. Participants provided written consent for participation in followup.

Outcomes

The primary outcome of treatment success was defined as no re-treatment for SUI (behavioral, pharmacological, pessary or surgical) and no self-reported SUI symptoms on the MESA questionnaire.[13] An answer of never or rarely to all stress specific questions was considered negative symptoms. Secondary outcomes included the Urogenital Distress Inventory and the Incontinence Impact Questionnaire.[14] Women also completed the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire[15] to assess sexual function, the Patient Global Impression of Improvement[16] to assess overall improvement, and 1 item satisfaction question, "How satisfied or dissatisfied are you with results of bladder surgery related to urine leakage?". Possible responses were completely satisfied, mostly satisfied, neutral, mostly dissatisfied and completely dissatisfied. Completely and mostly satisfied were reported as satisfied. Neutral, mostly dissatisfied and completely dissatisfied were reported as not satisfied.

Pelvic examinations were performed at annual visits to assess for visual and palpable evidence of mesh exposure, and to associate patient symptoms with physical findings. Prolapse was assessed using the Pelvic Organ Prolapse Quantification system.[17] Participants who were not seen in-person could mail in the completed questionnaires.

Adverse events were defined as deviation from normal postoperative followup and severity grade determined with modified Clavien-Dindo classification, which is based on level of therapy required to treat an event.[18] Nonserious adverse events (grades I and II) did not require surgical, endoscopic or radiological intervention. Serious adverse events required such intervention (grade III), were life threatening (grade IV) or resulted in death (grade V). Several adverse events were collected during the cohort study such as mesh exposure (mesh visualized in the vagina), mesh erosion (mesh erosion after primary healing into a nearby organ), vesical and urethral-vaginal fistulas, and recurrent urinary tract infections defined as 3 or more in 1 year.

Statistical Analysis

TOMUS had 80% power to show equivalence between the 2 procedures at 1 year with equivalence margins of ±12 percentage points at a 5% significance level.[11] We projected an initial enrollment in the cohort study of 400 women with 90% (360) completing 1 or more followup visits and 70% (280) completing each visit. This sample size provides 80% power to show equivalence at 5 years after surgery with equivalence margins of ±15 percentage points at a 5% significance level. Determination of equivalence requires the entire 95% CI for the difference between the 2 slings to be within the equivalence margin. Rates of treatment success and standard error rates were obtained using KM time to event analysis.

For this analysis we included all women randomized and treated per protocol in the equivalence trial since re-treatment was treatment failure and an exclusion criterion for observational study. Those who did not enroll in the cohort study were censored at the last trial visit at which outcome was assessed. To minimize bias toward determining equivalence, data from women who were treated per protocol (ie were eligible and received the assigned surgery) were included in the primary analysis.[19] The difference between groups was calculated using cumulative success rates from KM analysis. Confidence intervals of differences were calculated using standard errors from KM analysis, assuming independent groups and normal approximation to binomial distribution. Sensitivity analyses were performed in which different assumptions were made about the outcomes of women who were lost to followup. Fisher's exact test was used to compare the proportions of women in each group who had 1 or more adverse events.

Analysis of the secondary outcomes was performed including only the observational study sample. Continuous outcomes were analyzed with least squares modeling methods. Repeated measures modeling was used to assess changes over time after surgery by sling group controlling for baseline level of measures. Analyses were performed using SAS® statistical software, version 9.2.

RESULTS

Study Population

Of 597 women 404 (67.7%) from the original randomized trial enrolled in the observational followup. Overall 22 women (3.7%) were ineligible because of surgical re-treatment for SUI, 72 (12.1%) declined participation, 72 (12.1%) were lost to followup and 27 (4.5%) were not enrolled for other reasons (fig. 1). Women who enrolled were older (53.7±10.5 vs 51.2±11.8, p=0.02) and more likely to be postmenopausal (33.4% vs 18.8%, p=0.0009). Baseline clinical and demographic characteristics at randomized trial entry were similar in both surgery groups (supplementary table 1, http://jurology.com/).

Outcomes

To obtain accurate estimates of long-term treatment success all women randomized in the original trial who underwent the study surgery per protocol (583) were included in KM analysis (fig. 2). As seen in primary equivalence outcome, the retropubic sling had slightly better treatment success over time (log rank test p=0.09).

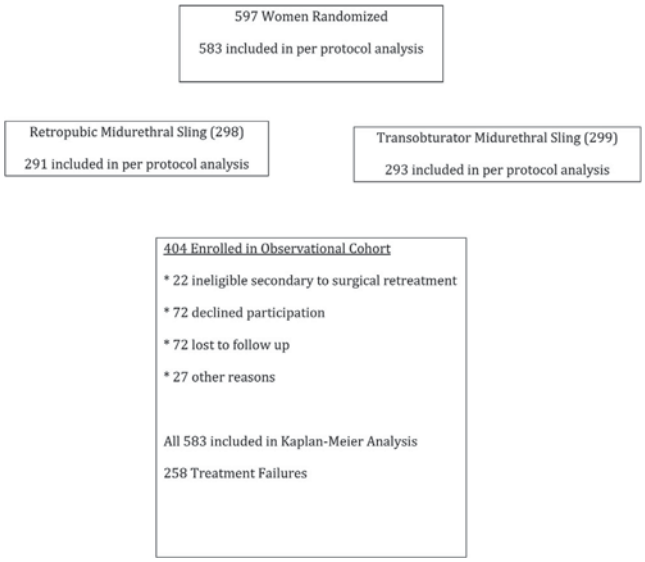

Figure 1. Flow diagram

Five years after surgery the treatment success was 7.9% greater after retropubic than transobturator sling (51.3% vs 43.4%, 95% CI −1.4, 17.2), and did not meet the prespecified criteria for equivalence of 12% in the original trial or 15% in the current study (fig. 3). However, confidence intervals included 0%, indicating that success rates also cannot be considered different from one another. Treatment failures were primarily due to SUI symptoms only (220), others were due to SUI symptoms and surgical re-treatment (37), and a single failure was attributed exclusively to surgical re-treatment. We also reestimated the 1 and 2-year treatment success rates and equivalence margins of the clinical trial using our definition of treatment success from the cohort study, and compared those rates to treatment success rates at 5 years (fig. 3). Recalculated 1 and 2-year treatment success rates are similar to originally reported subjective and objective success rates at 2 years.[12]

To assess the sensitivity of our results to loss to followup, we computed several analyses using different assumptions about the experiences of those not followed for 5 years (see table). Only the most extreme assumptions in favor of the retropubic sling resulted in a confidence interval that indicated superiority of the retropubic procedure. When all women who were lost to followup are assumed to be incontinent, the difference between groups is −0.9 (95% CI −8.0, 6.1) and the confidence interval lies

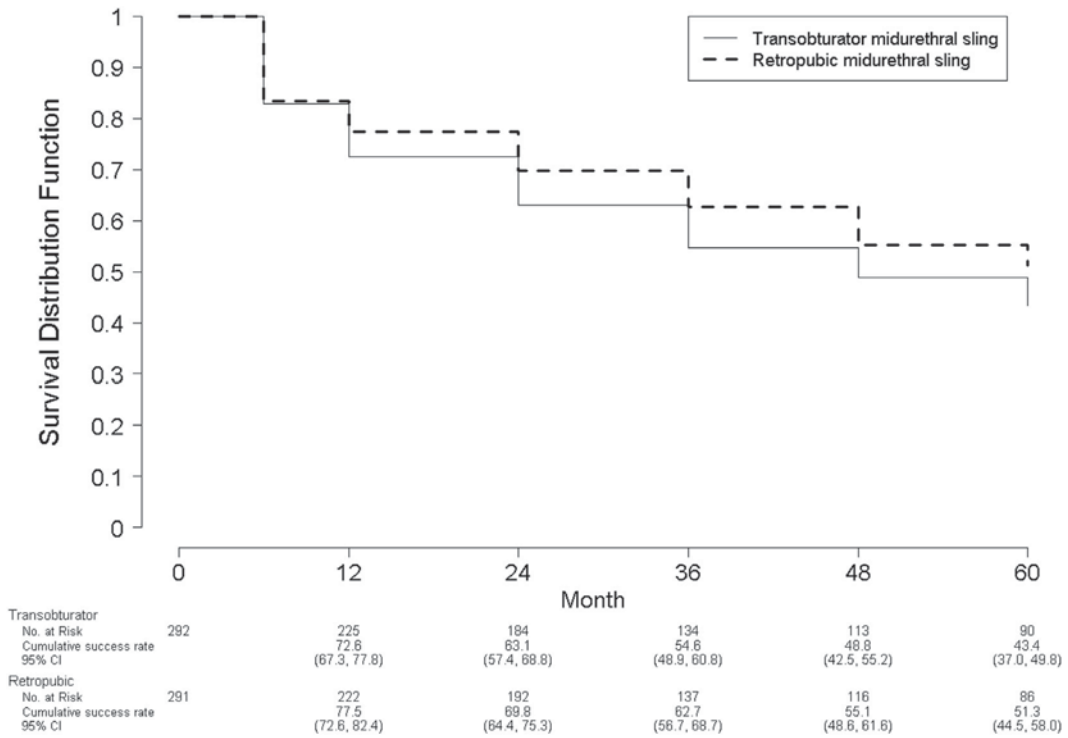

Figure 2. Treatment success rates over time

within the equivalence bounds. In this case the hypothesis of nonequivalence would be rejected. For most cases the confidence intervals cross the equivalence bounds and the results remain inconclusive.

Mean symptom distress and impact scores at baseline, 6 months and 5 years after surgery for the 404 women in the observational cohort by treatment group are shown in supplementary table 2 (http://jurology.com/). Urinary and sexual function measures improved after surgery, but there was a significant increase in these symptoms with time in both groups (although still improved compared to baseline). SUI symptoms as measured by MESA and Urogenital Distress Inventory measures pooled over all visits did not differ between the treatment groups (p=0.62 and p=0.08, respectively). However, urgency incontinence symptoms as measured by MESA were higher in the retropubic compared to the transobturator MUS group (p=0.001). For incontinence impact on QOL, trend over time differed significantly between the groups (p=0.02), with retropubic having a greater negative impact. The pattern of changes in incontinence impact from visit to visit differed between the groups. Among 271 women who reported they were sexually active after surgery, mean sexual function scores were lower (worse function) in the retropubic than in the transobturator group when pooled over postoperative visits (p=0.001).

The proportion of women who stated they were very much better or much better by the Patient Global Impression of Improvement decreased with time in both groups ($p < 0.0001$). However, a greater proportion of women in the transobturator group reported they were very much better or much better at 5 years (88% vs 77%, p=0.01). Women in the transobturator group were nearly twice as likely to report improvement in urinary condition compared to those in the retropubic group (OR 1.94, 95% CI 1.18, 3.21). Although patient satisfaction decreased significantly with time in both groups (retropubic 93% to 79% and transobturator 92% to 85%, $p < 0.0001$), there was no significant difference between the groups at 5 years (p=0.15).

Adverse Events

During the observational cohort study 40 women (10%) experienced 52 nonserious adverse events and 6 serious adverse events. There was no difference between the groups in the proportion of women who experienced at least 1 adverse event (12% in retropubic vs 8% in transobturator, p=0.17). The 6 serious adverse events which required surgical, radiological or endoscopic intervention (grade III) included 2 mesh erosions (1 in each group) and 4 recurrent urinary tract infections (all in the retropubic group). The 52 nonserious adverse events

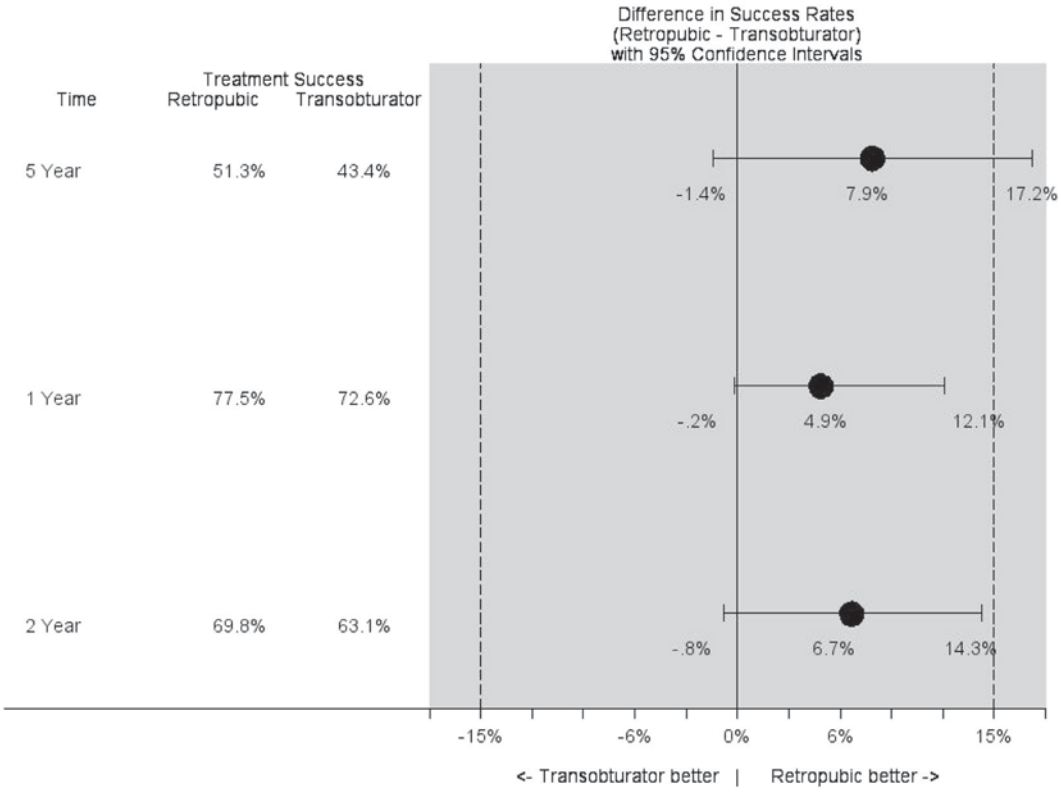

Figure 3. Treatment success and 95% CIs for retropubic and transobturator MUS at 1, 2 and 5 years after surgery

were primarily urinary tract infections (37) followed by mesh exposures (7), with the remainder being pain, vaginal discharge, decreased bladder sensation and numbness.

Of 52 nonserious adverse events 5 were reported in the clinical trial and were followed for 5 years, including 2 persistent mesh exposures (1 in each group), 2 cases of continuing neurological symptoms (transobturator) and 1 case of seroma. Overall there were 7 new mesh exposures in postoperative years 3 to 5 (retropubic 3 and transobturator 4, p=0.71). Recurrent urinary tract infections (41) were reported by 25 women (6%), including 17 (8%) in the retropubic group and 8 (4%) in the transobturator group (p=0.06).

DISCUSSION

Women from a well characterized, randomized equivalence surgical trial enrolled in a longitudinal observational cohort demonstrated decreasing continence success rates after retropubic and transobturator MUS during the first 5 years after treatment. Treatment success was slightly higher after the retropubic vs transobturator sling and did not meet the prespecified criteria for equivalence. However, confidence intervals included 0%, indicating that success rates cannot be considered different from one another. Similar to our 2-year findings,[12] long-term treatment success after retropubic MUS continued to be slightly higher than after transobturator MUS, while urinary urgency incontinence,

Overall treatment success at 5-year visit

	No. Retropubic (%)	No. Transobturator (%)	Difference (%)	95% CI
Complete cases*	72 (38.1)	75 (34.6)	3.5	−5.9, 12.9
Sensitivity analyses:†				
All treatments:				
Lost = success	174 (59.8)	150 (51.4)	8.4	0.4, 16.5
Lost = failure	72 (24.7)	75 (25.7)	−0.9	−8.0, 6.1
Retropubic: lost = success; transobturator: lost = failure	174 (59.8)	75 (25.7)	31.4	26.6, 41.7
Retropubic: lost = failure; transobturator: lost = success	72 (24.7)	150 (51.4)	26.7	34.2, −19.1

* Observational cohort failure status at 5 years is known. Those who did not consent or were lost to followup before completing the 5-year visit were excluded from analysis.
† Different assumptions about status of those who did not consent to observational cohort or were lost to followup.

sexual function and overall impression of improvement were better after transobturator MUS.

Patient reported outcomes for QOL, sexual function and global assessment of improvement also decreased with time but remained significantly improved compared to baseline. While satisfaction decreased after both procedures, it decreased less than actual continence success rates, suggesting that satisfaction is influenced by other urogenital functional outcomes. Our satisfaction rates at 5 years are similar to the rates (83%) reported in a Cochrane Review comparing retropubic and transobturator slings at 1 year.[20] Longer term data are not included in the Cochrane Review, demonstrating the marked importance of the current data.

Although treatment success rates were slightly higher after retropubic sling, a greater proportion of women who underwent a transobturator sling procedure reported that urinary status was very much better or much better. This perception of greater overall improvement despite more SUI symptoms may be explained by higher rates of urgency urinary incontinence and irritative symptoms in women after retropubic sling, which essentially equalized the slight advantage of retropubic over transobturator sling with respect to treatment success. In general, urinary symptoms and quality of life measures showed greater overall improvement after transobturator sling, suggesting that the trend toward favoring better treatment success in the retropubic group may come at the cost of quality of life and other symptom improvement.

These findings are similar to those seen in extended followup of the Stress Incontinence Surgical Treatment Efficacy Trial, a multicenter, randomized trial which compared Burch colposuspension to pubovaginal sling using autologous rectus fascia.[4] Fascial sling had slightly higher 5-year continence rates than the Burch but, similar to the current study, satisfaction trends over time did not differ significantly between the 2 treatments. Investigators reported that urgency urinary incontinence may contribute significantly to patient perceptions of satisfaction.[4,21] Clearly there are other factors including urgency incontinence which contribute to satisfaction and perception of overall improvement, and may partially explain the disparity between treatment success rates and improvement and satisfaction. More urgency incontinence or voiding symptoms may be the trade-off in the longer term for higher treatment success with these procedures.

The large cohort with annual in-person pelvic examinations to assess mesh exposures is an important contribution. Although a few women experienced new mesh exposures, the numbers remain reassuringly small (1.7%). While rates of new mesh exposures are not unacceptably high and are comparable to rates seen with polypropylene abdominal sacrocolpopexy,[22] they illustrate the ongoing risks of mesh erosion even 5 years from initial sling placement. Clearly mesh exposure is not limited to the immediate postoperative period and this adverse effect should be a consideration remote from the initial placement of mesh.

Early in the introduction of polypropylene slings, surgeons suggested that the use of permanent mesh would result in more durable outcomes compared to procedures with autologous, donor allograft and xenograft slings. Our data refute that initial belief. Just as with biological materials, permanent mesh slings show a progressive decrease in efficacy with time.

Our results are robust due to a well-defined surgical cohort followed closely at multiple centers across the country, and assessed using standardized and validated measures including an annual physical examination to assess mesh complications. Limitations include a slightly lower retention rate (67%) compared to the original trial. Therefore, mesh exposures may be slightly higher than reported, although our previous trial revealed a lower proportion of continent women entered extended followup, suggesting that adverse events may not be overrepresented in the study population.[4]

Long-term treatment success and satisfaction with retropubic and transobturator MUS decrease with time, and mesh complications continue to increase at a low rate. Women undergoing transobturator MUS reported more sustained improvement in urinary symptoms, QOL and sexual function despite the slightly lower treatment success rates. These data are important for physicians and patients as rates of MUS procedures continue to increase, with some even suggesting that slings be offered as a first line treatment for SUI.[23]

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REFERENCES

1. Oliphant SS, Wang L, Bunker CH et al: Trends in stress urinary incontinence inpatient procedures in the United States, 1979-2004. Am J Obstet Gynecol 2009; **200:** 521.
2. Erekson EA, Lopes VV, Raker CA et al: Ambulatory procedures for female pelvic floor disorders in the United States. Am J Obstet Gynecol 2010; **203:** 497.
3. Anger JT, Weinberg AE, Albo ME et al: Trends in surgical management of stress urinary incontinence among female Medicare beneficiaries. Urology 2009; **74:** 283.
4. Brubaker L, Richter HE, Norton PA et al: 5-Year continence rates, satisfaction and adverse events of Burch urethropexy and fascial sling surgery for urinary incontinence. J Urol 2012; **187:** 1324.
5. Ward KL and Hilton P: Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008; **115:** 226.
6. Tsivian A, Mogutin B, Kessler O et al: Tension-free vaginal tape procedure for the treatment of female stress urinary incontinence: long-term results. J Urol 2004; **172:** 998.
7. Jelovsek JE, Barber MD, Karram MM et al: Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008; **115:** 219.
8. Ballester M, Bui C, Frobert JL et al: Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes. World J Urol 2012; **30:** 117.
9. Nilsson CG, Kuuva N, Falconer C et al: Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct, suppl., 2001; **12:** S5.
10. Schierlitz L, Dwyer PL, Rosamilia A et al: Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. Obstet Gynecol 2012; **119:** 321.
11. Richter HE, Albo ME, Zyczynski HM et al: Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 2010; **362:** 2066.
12. Albo ME, Litman HJ, Richter HE et al: Treatment success of retropubic and transobturator mid urethral slings at 24 months. J Urol 2012; **188:** 2281.
13. Herzog AR, Diokno AC, Brown MB et al: Two-year incidence, remission, and change patterns of urinary incontinence in noninstitutionalized older adults. J Gerontol 1990; **45:** M67.
14. Shumaker SA, Wyman JF, Uebersax JS et al: Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program in Women (CPW) Research Group. Qual Life Res 1994; **3:** 291.
15. Rogers RG, Coates KW, Kammerer-Doak D et al: A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Int Urogynecol J Pelvic Floor Dysfunct 2003; **14:** 164.

16. Yalcin I and Bump RC: Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003; **189:** 98.

17. Bump RC, Mattiasson A, Bo K et al: The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996; **175:** 10.

18. Dindo D, Demartines N and Clavien PA: Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004; **240:** 205.

19. Brittain E and Lin D: A comparison of intent-to-treat and per-protocol results in antibiotic non-inferiority trials. Stat Med 2005; **24:** 1.

20. Ogah J, Cody JD and Rogerson L: Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev 2009; CD006375.

21. Burgio KL, Brubaker L, Richter HE et al: Patient satisfaction with stress incontinence surgery. Neurourol Urodyn 2010; **29:** 1403.

22. Nygaard IE, McCreery R, Brubaker L et al: Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol 2004; **104:** 805.

23. Labrie J, Berghmans BL, Fischer K et al: Surgery versus physiotherapy for stress urinary incontinence. N Engl J Med 2013; **369:** 1124.